

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

The Office Action Summary correctly indicates that claims 44-63 and 65-81, as renumbered in the Office Action, are pending in the application. Claims 44-63 and 65-81 are under consideration and stand rejected.

By the present amendment, the specification is amended to correct an obvious error in the paragraph bridging pages 9-10, which begins at page 9, line 30. In the original paragraph, one incidence of "E6" should have been "E7" where the paragraph describes SEQ ID NO: 2. The error would be immediately apparent to one skilled in the art upon comparing this paragraph with the original Sequence Listing and Example 3, where SEQ ID NO: 2 is correctly described. Thus, the correction does not introduce any new matter.

The heading "Brief Description of the Drawings" is inserted before the paragraph beginning at page 27, line 27.

The Abstract has been rewritten as suggested in the Office Action. The amendment to the Abstract cannot be construed as affecting the scope of the disclosure in any way.

The claim listing reflects the renumbering of claims 55-81 set forth in the Office Action. Claims 44, 46, 48, 50-56, 59-60, 65, 70-71 and 78 have been canceled without prejudice or disclaimer of the subject matter described therein. Claims 45, 47, 49, 58, 61-63, 66-69, 72-77 and 79-81 have been amended.

Claims 45 and 47 have each been amended to be in independent form by incorporating the subject matter of claim 44. Claims 45, 47, 49, 61 and 72 also now explicitly recite that the composition may be based on a recombinant vector or a viral particle

comprising the recited vector, as described throughout the specification, for example, at page 27, lines 11-17. The word "having" in claims 49 and 61 has been replaced with the synonymous "comprising" as suggested in the Office Action. The article "a" has been inserted in claim 61 where grammatically appropriate. The dependencies of claims have been amended in view of the renumbering of claims 55-81 and in view of claim cancellations.

Claims 82-94 are added. Support for claims 82-89 can be found throughout the specification and original claims, for example, as previously described for claims 46, 48, 50-54 and 65, respectively. Support for claims 90-92 can be found throughout the specification and original claims, for example as previously described for claims 79-81, respectively. Support for claims 93-94 can be found throughout the specification and original claims, for example as previously described for claims 63 and 66, respectively.

No prohibited new matter has been introduced by way of the above amendments. Applicants reserve the right to file a continuation or divisional application on any subject matter that has been canceled by way of this Amendment.

Objections to the Specification

The specification was objected to for lack of a heading of "Brief Description of the Drawings." By the present amendment, the heading "Brief Description of the Drawings" is inserted before the paragraph beginning at page 27, line 27.

The Abstract was objected to. The Office Action provides guidelines for the form and language of the Abstract. The Abstract has been rewritten with a view to the guidelines suggested in the Office Action. Of course, because of its abbreviated nature, the Abstract should not be considered as limiting the scope of the disclosure in any way. Therefore, the amendment to the Abstract cannot be construed as affecting the scope of the disclosure.

Withdrawal of the objections to the specification is respectfully requested.

Claim Objections

The numbering of claims 55-81 was objected to and claims that had been previously presented as claims 56-82 were renumbered as 55-81 in the Official Action. The claims listing of the present Amendment and Reply reflect the renumbering of the claims; dependant claims have been amended to preserve the intended dependencies where appropriate.

Claims 44 and 45 have been objected to for reciting “the E6 and E7 early region of a HPV-16 papillomavirus genome.” It is alleged that applicants have not specifically provided support in the specification for such a recitation. The Office Action suggests that Markush type language indicating that either an E6 or E7 polypeptide may be selected may obviate the rejection.

It should be noted that claims 44 and 45, as previously presented, actually recited “the E6 or E7 early region of a HPV-16 papillomavirus genome.” By the present amendment, claim 44 has been canceled, the subject matter thereof being inserted into claim 45, which has been rewritten in independent form.

Claim 45, as amended, recites a “recombinant vector comprising a sequence encoding at least one immunogenic polypeptide encoded by the E6 or E7 early region of a HPV-16 papillomavirus genome.” Claim 45 further recites “wherein said immunogenic polypeptide encoded by the E6 or E7 early region of a HPV-16 papillomavirus genome naturally has a nuclear location and wherein its natural nuclear localization sequence is deleted.” Thus claim 45 refers to a vector comprising a sequence encoding a polypeptide encoded by the E6 early region of a HPV-16 papillomavirus genome or a sequence encoding a polypeptide encoded by the E7 early region of a HPV-16 papillomavirus genome where the recited polypeptide

naturally has a nuclear location and wherein its natural nuclear localization sequence is deleted. Vectors having combinations of the recited features are described throughout the specification including exemplary embodiments thereof. With respect to the recited polypeptides, see, for example, the specification at page 9, lines 30-33. It is respectfully submitted that the subject matter of claim 45 is both sufficiently clear and described by the specification such that the requirements of 35 U.S.C. § 112 are satisfied.

Claim 49 was objected to for the recitation of "having." Without agreeing that such an amendment was required for patentability, but simply in order to expedite prosecution, recitations of "having" in the claims have been replaced with the synonymous "comprising," where appropriate, as suggested by the Office Action.

Claim 61 has been objected to as allegedly needing an article preceding "sequence" in three instances. Without agreeing that such an amendment is required for patentability, but simply in order to expedite prosecution, the article "a" is inserted in claim 61 where appropriate.

Claims 62 and 67 have been objected to, because the recited "compound" should allegedly be replaced with "polypeptide." Without agreeing that such an amendment is required for patentability, but simply in order to expedite prosecution, the recitation of compound has been replaced with "polypeptide."

Claims 63, 66, 68, 69 and 77 have been objected to as being dependant upon a rejected base claim. Claims 63, 66, 68, 69 and 77 depend directly or indirectly from claim 49, which has been indicated as free from the prior art. The objection to claim 49 has been obviated as described above.

In view of at least the foregoing, withdrawal of the claim objections is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 44-48, 50-60, 65, 70, 71, 76, 78-81 have been rejected under 35 U.S.C. §§ 112 and 132, as allegedly containing subject matter that was not described in the specification. Claims 44, 46, 48, 50-56, 70, 71 and 78 have been canceled without prejudice or disclaimer of the subject matter described therein. Claims 45, 47, 49, 58, 61-63, 66-69, 72-77 and 79-81 have been amended. To the extent that the rejection might be alleged apply to the claims as currently presented, the rejection is respectfully traversed.

The Office Action asserts as the reason for the rejection that claim 44 recited “non-integrative vector,” and alleges that the specification fails to define the term and that Applicants failed to specifically point out support for this recitation. The term is now recited in claims 45 and 47. Applicants submit that the use of non-integrative vectors is described throughout the specification through both exemplary embodiments and explicit description. For example, the use of a non-integrative vector is explicitly described at page 14, line 31, of the specification. The term “non-integrative vector” is a term of art that one of skill in the field would understand as designating a vector that is not in the class of vectors designed to integrate DNA sequences into the genome of a host cell. Claims 45 and 47, as well as their respective dependant claims, are sufficiently described in the specification in compliance with 35 U.S.C. § 112, first paragraph.

For at least the foregoing reasons, withdrawal of the rejection of claims 44-48, 50-60, 65, 70, 71, 76, 78-81 is respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph

Claim 44 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite, because it is asserted to be unclear whether the phrase starting with “which is

modified . . .” refers to the genome or immunogenic polypeptide. Claim 44 has been canceled. Claims 45 and 47 have been rewritten in independent form by incorporating language from claim 44. Claims 45 and 47, as amended, recite “wherein said immunogenic polypeptide is modified.”

Claim 46 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite, for recitation of “and/or.” Without agreeing to the rejection claim 46 has been canceled. New claim 82 recites language that formerly appeared in claim 46, but does not recite “and/or.”

Claims 47, 59, 60 and 72 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite, because it is alleged that there are many different sequences of HPV-E6 or E7. Claims 59 and 60 have been canceled. Applicants respectfully point out that the present claims refer specifically to HPV-16 and that only one HPV-16 genome (Accession No. NC_001526) appears in the cited NCBI database listing. All other sequences on the cited listing refer to other HPV serotypes. Thus, the evidence purported to support the rejection does not show multiple HPV-16 E6 or E7 sequences.

Sequences of the E6 and E7 polypeptides of HPV-16 were known at the time the application was filed. The deletions recited in claims 47 and 72 refer to positions in the known sequences of the E6 and E7 polypeptides of HPV-16. Example 1 of the Specification provides an exemplary construction of such variants of E6 and E7 of HPV-16 with reference to a specific starting material that is described in the patent literature.

Moreover, even to the extent that variations in the HPV-16 genome may exist, the Office Action has not demonstrated that any variation is such that the position of the residues to be deleted recited in the claims would not be clear to one skilled in the art. Thus, one skilled in the art would understand the metes and bounds of the claims as written.

Claim 47 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for recitation of "said E6 polypeptide." Without agreeing with the alleged reason for the rejection, claim 47 has been rewritten in independent form by incorporating language from claim 44. Claim 47 as amended does not recite "said E6 polypeptide." Claim 47, as amended, recites ". . . the polypeptide encoded by the E6 early region of a HPV-16 papillomavirus genome wherein residues 111 to 115 are deleted. . . ." The metes and bounds of claim 47 would be apparent to one of skill in the art.

Claim 55 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Without agreeing with the alleged reason for the rejection, claim 55 has been canceled. Thus, the rejection is moot.

For at least the forgoing reasons, withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 44, 46, 48, 50-56, 70, 71 and 78 has been rejected under 35 U.S.C. § 103 as allegedly unpatentable over Andrew et al. (1990, J. Virol. 64, 4776-83) in view of Boursnell et al. (1996, Vaccine 14, 1485-94), Borysiewicz et al. (1996, Lancet 347, 1523-27) and Stanley et al. (U.S. Patent No. 6,096,869). Claim 65 has been rejected under 35 U.S.C. § 103 as allegedly unpatentable over Andrew et al. (1990, J. Virol. 64, 4776-83) in view of Boursnell et al. (1996, Vaccine 14, 1485-94), Borysiewicz et al. (1996, Lancet 347, 1523-27) and Stanley et al. (U.S. Patent No. 6,096,869) and further in view of Sutter et al. (1994, Vaccine 12, 1032-40). Without agreeing with the reasons alleged for the rejections, claims 44, 46, 48, 50-56, 59-60, 65, 70-71 and 78 have been canceled without prejudice or disclaimer of the subject matter described therein. Accordingly, the rejection is moot.

Claims 45, 47, 49, 57-63, 66-69, 72-75, 77 and 79-81 have been indicated as free from the prior art. Claims 45 and 47, as presently amended, are rewritten in independent form. New claims 82-94 depend directly or indirectly from claims 45, 47 and 61 and thus incorporate all the limitations thereof. Therefore, all currently pending claims are free of the prior art as indicated in the Official Action

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

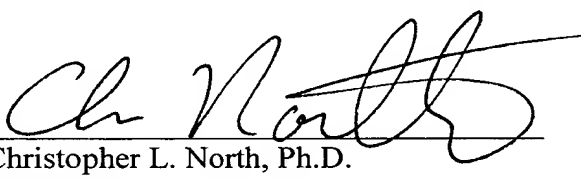
In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: August 17, 2004

By:



Christopher L. North, Ph.D.
Registration No. 50,433

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620